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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,827

10/10/2006

Masahiro Yamauchi

2006\_1488A

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513 7590 06/21/2010  
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EXAMINER

EPSS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

06/21/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
coa@wenderoth.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,827	<b>Applicant(s)</b> YAMAUCHI ET AL.	
	<b>Examiner</b> Janet L. Epps-Smith	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03-17-2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39,40,42 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39,40,42 and 48-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-38, 41, 43-47 and 49 were cancelled by Applicants. Claims 39-40, 42 and 48, 50 are pending for examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 102***

3. The rejection of claims 39-40, 42, and 48-50 under 35 U.S.C. 102(b) as being anticipated by Kato et al. (US20040022938), is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 39-40, 42, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (US20040022938).
6. Applicant's arguments filed 03/17/2010 have been fully considered but they are not persuasive. Applicants traversed the rejection of the instant claims over Kato et al. on the grounds that (1) Kato does not expressly teach the combination of a nucleic acid and an anionic polymer with liposome; or (2) Kato et al. does not disclose plasmids and siRNA. Furthermore, Applicants refer to Examples 13 and 15-17 to conclude that

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coating of the complex particles with the coating lipid is efficient, and therefore is preferred to the preparation of Example 13 (without anionic polymer).

Contrary to Applicant's assertions, although Kato et al. does not expressly describe a complex of plasmid or siRNA, liposome and anionic polymer, Kato et al. discloses a method for coating fine particles with lipid membrane, wherein the fine particles comprise a complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt, (¶ [0020]). Furthermore, Kato et al. teaches wherein the drug is a nucleic acid, and further wherein said nucleic acid is a gene (see ¶ [0030]), antisense oligonucleotide, sense oligonucleotide, DNA and RNA. Absent evidence to the contrary, it would have been obvious to substitute alternative, structurally equivalent forms of nucleic acid, such as plasmid or siRNA for the forms of nucleic acid used in the complexes of Kato et al. It is clear that the novelty of the claimed invention is not associated with the class of nucleic acid, as evidenced by ¶ [0018] of the specification as filed, which recites: "[T]he method of inhibiting aggregation of complex particles according to the above (8), wherein the nucleic acid as the drug is one or more substance(s) selected from genes, DNA, RNA, oligonucleotides, plasmids and siRNA." Therefore, the selection of plasmid or siRNA as the nucleic acid in the complexes of the claimed invention is simply a matter of design choice.

Additionally, in regards to the increase in efficiency observed due to the presence of anionic polymer in Examples 15-17 of the specification as filed, Applicants have not provided any evidence that this observation is unexpected in light of the teachings of Kato et al.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633